Appl. No. : **09/989,684**
Filed : **November 20, 2001**

AMENDMENTS TO THE CLAIMS

1. (Withdrawn) An optical disc for separating disperse particles from particle agglutinants, comprising a separation zone structure having solid components spaced apart to form gaps, the gaps being large enough to allow disperse particles to change position relative to the center of the disc by passing through the separation zone structure, the gaps being too small to allow particle agglutinants to pass through the separation zone structure.

2. (Withdrawn) The disc of claim 1, further comprising:

a chamber for holding an organic specimen having disperse particles and particle agglutinants, the chamber being in communication with the separation zone structure.

3. (Withdrawn) The disc of claim 1, further comprising:

an information storage mechanism having result data derived from a test performed on the disc.

4. (Withdrawn) The disc of claim 1, further comprising:

an information storage mechanism having instruction data directed to a procedure for use with the disc.

5. (Withdrawn) Rotating apparatus for separating disperse particles from particle agglutinants, comprising a separation zone structure having solid components spaced apart to form gaps, the gaps being large enough to allow disperse particles to change position relative to the center of rotation by passing through the separation zone structure, the gaps being too small to allow particle agglutinants to pass through the separation zone structure.

6. (Withdrawn) The apparatus of claim 5, further comprising:

a chamber for holding an organic specimen having disperse particles and particle agglutinants, the chamber being in communication with the separation zone structure.

7. (Withdrawn) The apparatus of claim 5, further comprising:

an information storage mechanism having result data derived from a test performed on the apparatus.

8. (Withdrawn) The apparatus of claim 5, further comprising:

an information storage mechanism having instruction data directed to a procedure for use with the apparatus.

9. (Currently Amended) An optical disc, comprising:

a microfluidic circuit that is responsive to centrifugal force resulting from rotation of the disc, the circuit comprising:

an entry chamber positioned proximate a center of the optical disc and ~~an entry chamber for~~ configured to hold ~~holding~~ a specimen having disperse particles and particle agglutinants; ~~and~~

a collection zone positioned promixate an outer edge of the optical disc;

a separation structure positioned between the entry chamber and the collection zone, the separation ~~zone~~ structure ~~disposed downstream of the entry chamber, the specimen being urged toward the separation zone structure by the centrifugal force, the separation zone structure having~~ comprising a plurality of structures that define gaps therebetween, the distance between the gaps being less than or equal to the width of the particle agglutinants, the separation structure being configured to separate particle agglutinants from the disperse particles when the specimen is urged toward the separation structure by centrifugal force created when the optical disc is rotated; and ~~large enough to allow disperse particles to escape the entry chamber, the gaps being small enough to retain particle agglutinants in the entry chamber.~~

a tracking groove positioned at least partly beneath the entry chamber and proximate the separation structure, wherein particle agglutinants in the entry chamber can be quantified by determining an amount of the tracking groove that is at least partly covered by particle agglutinants.

10. (Canceled)

11. (Canceled)

12. (Currently Amended) The optical disc of claim 9 ~~11~~, further comprising a collection tracking groove positioned in the collection zone, wherein the presence of the disperse particles in the collection zone can be determined by coverage of the collection tracking groove by disperse particles ~~wherein when the substrate is rotated the presence of disperse particles can be determined by the coverage of the tracking groove by disperse particles in the collection zone~~.

13. (Canceled)

14. (Canceled)

15. (Currently Amended) The optical disc of claim 9 ~~10~~, wherein the separation ~~zone~~ structure includes a series of slits formed in the optical disc ~~substrate~~, each slit having a

predetermined width that allows disperse particles to pass therethrough while causing particle agglutinants to be retained in the entry chamber ~~collection zone~~.

16. (Currently Amended) The optical disc of claim 15, wherein the slits are formed by a series of rib structures ~~disposed in the separation zone structure~~.

17. (Currently Amended) The optical disc of claim 16, wherein the ~~structures forming~~ ~~the~~ series of rib structures are substantially parallel to each another.

18. (Currently Amended) The optical disc of claim 16, wherein the ~~structures forming~~ ~~the~~ series of rib structures are radially directed from the center of the disc.

19. (Original) The optical disc of claim 10, wherein the predetermined width of each slit decreases as a function of increasing distance from the center of the disc.

20. (Original) The optical disc of claim 18, wherein each of the rib structures has a width that increases as a function of increasing distance from the center of the disc.

21. (Currently Amended) The optical disc of claim 9 ~~14~~, wherein each of the structures comprises a post ~~wherein each post has~~ having a predetermined diameter.

22. (Currently Amended) The optical disc of claim 21, wherein ~~for posts along a radius from the center of the disc along the substrate, the~~ a diameter of consecutive posts increases as a function of increasing distance from the center of the disc.

23. (Currently Amended) The optical disc of claim 21 ~~14~~, wherein the number of posts per unit area increases as a function of increasing distance from the center of the disc.

24. (Original) The optical disc of claim 15, wherein the width of the slits decreases as a function of increasing distance from the center of the disc.

25 (Currently Amended) The optical disc of claim 9, wherein the structures comprise ~~separation zone structure includes~~ a filter having a preselected porosity so that when the optical disc is rotated, disperse particles escape from the entry chamber and particle agglutinants are retained in the entry chamber.

26. (Original) The optical disc of claim 25, wherein the filter is formed from a material selected from the group consisting of glass fiber and plastic fiber.

27. (Original) The optical disc of claim 26, wherein the glass fiber is formed from a material selected from the group consisting of alumina, silica, and quartz.

28. (Original) The optical disc of claim 26, wherein the plastic fiber is formed from a material selected from the group consisting of cellulose acetate, cellulose nitrite, mixed cellulose

esters, polyethersulfone polyvinyl chloride, polycrylonitrile, polycarbonate, polysulfone, polyfluorotetra-ethylene, polyvinylidene-fluoride, and cellulose.

29. (Original) The optical disc of claim 25, wherein the filter is formed from a material selected from the group consisting of glass particles and plastic particles.

30. (Original) The optical disc of claim 29, wherein the glass particles are formed from a material selected from the group consisting of alumina, silica, and quartz.

31. (Original) The optical disc of claim 29, wherein the plastic particles are formed from a material selected from the group consisting of cellulose acetate, cellulose nitrite, mixed cellulose esters, polyethersulfone polyvinyl chloride, polycrylonitrile, polycarbonate, polysulfone, polyfluorotetra-ethylene, polyvinylidene-fluoride, and cellulose.

32. (Withdrawn) A method of using an optical disc comprising a microfluidic circuit that is responsive to centrifugal force resulting from rotation of the disc, the circuit comprising an entry chamber for holding a specimen having disperse particles and particle agglutinants; and a separation zone structure disposed downstream of the entry chamber, the specimen being urged toward the separation zone structure by the centrifugal force, the separation zone structure having gaps, the gaps being large enough to allow disperse particles to escape the entry chamber, the gaps being small enough to retain particle agglutinants in the entry chamber, the method comprising:

dispensing a biological sample material into the entry chamber;

dispensing an assay reagent including particles coated with at least one type of bioactive agent into the entry chamber;

mixing the biological sample material with the assay reagent;

allowing the biological sample material to react with the assay reagent to thereby facilitate formation of an agglutinant; and

rotating the optical disc so that non-agglutinated particles escape from the entry chamber through the separation zone structure.

33. (Withdrawn) The method of claim 32, wherein the optical disc has optical disc tracks and further comprises a collection zone disposed downstream of the separation zone structure and between the optical disc tracks and a light detector, the method further comprising:

determining a quantity of disperse particles by using the light detector to count the number of optical disc tracks in the collection zone covered by the disperse particles and performing a volume calculation based on the track count.

34. (Withdrawn) The method of claim 32, wherein the optical disc has optical disc tracks and the entry chamber is disposed between the optical disc tracks and a light detector, the method further comprising:

determining a quantity of particle agglutinants by using the light detector to count the number of optical disc tracks in the entry chamber covered by the particle agglutinants and performing a volume calculation based on the track count.

35. (Withdrawn) The method of claim 32, wherein the particles coated with the at least one bioactive agent comprises microparticles.

36. (Withdrawn) The method of claim 32, wherein the particles coated with the at least one bioactive agent comprises latex material.

37. (Withdrawn) The method of claim 32, further comprising diluting the biological sample material.

38. (Withdrawn) The method of claim 32, further comprising preprocessing the biological sample material.

39. (Withdrawn) The method of claim 32, wherein the particles coated with the at least one bioactive agent comprise polystyrene material.

40. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for use in a serological assay.

41. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for use in bacterial identification.

42. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for use in viral identification.

43. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for use in amoebic identification.

44. (Withdrawn) The disc of claim 1, further comprising:

tracks disposed proximal the separation zone structure, wherein the presence of material on a first side of the separation zone structure may be detected by analyzing a result of directing a light beam toward the tracks.

45. (Withdrawn) The disc of claim 44, wherein the tracks are disposed such that in operation the entrance to the separation zone structure is interposed between the tracks and a light beam detector.

46. (Withdrawn) The disc of claim 44, wherein the tracks are disposed such that in operation the tracks are interposed between the entrance to the separation zone structure and a light beam detector.

47. (Withdrawn) The disc of claim 44, further comprising a collection zone disposed downstream of the separation zone structure, wherein the tracks are disposed such that in operation the collection zone is interposed between the tracks and a light beam detector.

48. (Withdrawn) The disc of claim 44, further comprising a collection zone disposed downstream of the separation zone structure, wherein the tracks are disposed such that in operation the tracks are interposed between the collection zone and a light beam detector.

49. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for cardiolipin.

50. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for rheumatoid factor.

51. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for d-dimer.

52. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for e. coli 157.

53. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for c. difficile.

54. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for c. jejuni.

55. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for c. coli.

56. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for c. laridis.

57. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for meningitis.

58. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for H. Pylori.

59. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for C. Neoformans.

60. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for N. Gonorhoeae.

61. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Staphlococcus Aureus.

62. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for S. Pneumoniae.

63. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Streptococcus A.

64. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Streptococcus B.

65. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Streptococcus C.

66. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Streptococcus F.

67. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Streptococcus G.

68. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Mycoplasma.

69. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Rubella.

70. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Varicella-Zoster Virus.

71. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Mononucleosis.

72. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Cytomegalovirus.

73. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Lupus Erythematosus.

74. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Cryptosporidium

75. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for Giardia.

76. (Withdrawn) The method of claim 32, wherein the at least one bioactive agent has specificity for C-Reactive Protein.

77. (Currently Amended) An optical disc for separating disperse particles from particle agglutinants, comprising:

a plurality of tracks disposed on an outer periphery of the optical disc;

a main chamber disposed between at least a portion of the plurality of tracks and a light detector, the main chamber comprising:

an entry chamber configured to accept a sample; and

~~having~~ a separation ~~zone~~ structure comprising ~~having~~ solid components spaced apart to form gaps, the gaps being large enough to allow disperse particles to change position relative to the center of the disc by passing through the separation ~~zone~~ structure, the gaps being too small to allow particle agglutinants to pass through the separation ~~zone~~ structure;

wherein a quantity of disperse particles may be determined by using the light detector to count a number of the plurality of tracks that are covered by the disperse particles

~~a mixing chamber in communication with the main chamber; and~~

~~a target area in communication with the mixing chamber~~.

78. (Currently Amended) An optical disc for separating disperse particles from particle agglutinants, comprising:

a plurality of tracks disposed proximate a central portion of the optical disc;

a main chamber~~;~~ disposed between at least a portion of the plurality of tracks and a light detector, the main chamber comprising:

an entry chamber configured to accept a biological sample and an assay reagent, wherein the biological sample and the assay reagent are mixed to form particle agglutinates and disperse particles;

a collection zone configured to contain disperse particles; and

~~a mixing chamber in communication with the main chamber, the mixing chamber having~~ a separation ~~zone~~ structure having solid components spaced apart to form gaps, the gaps being sized so that particle agglutinates are retained in the entry chamber while ~~large enough to allow~~ disperse particles are allowed to pass through the separation structure into the collection zone when the optical disc is rotated, ~~to change position relative to the center of the disc by passing through the separation zone structure, the gaps being too small to allow particle agglutinants to pass through the separation zone structure; and~~

~~a target area in communication with the mixing chamber~~

wherein a quantity of particle agglutinates may be determined by using the light detector to count a number of the plurality of tracks that are covered by the particle agglutinates.

79. (Canceled)

80. (Withdrawn) A method of using an optical disc comprising a microfluidic circuit that is responsive to centrifugal force resulting from rotation of the disc, the circuit comprising a chamber for holding a specimen, the specimen being urged outward from the center of rotation by the centrifugal force, the disc having tracks disposed in a line intersecting the chamber and a beam detector, the method comprising:

detecting whether a beam intersecting the chamber and a track has been affected by the presence of the specimen in the chamber; and

calculating a volume of the specimen based on the detection.

81. (Canceled)

82. (Withdrawn) An optical disc for separating disperse particles from particle agglutinants, comprising:

a main chamber having a separation structure that defines first and second separation zones so that pieces of material having a first size are retained in the first separation zone and other pieces of material having a second size pass through the separation structure to the second separation zone, the size of the first separation zone relative to the size of the second separation zone beng substantially commensurate with the relative proportions of components of an expected sample; and

a track disposed in a line intersecting at least one of the first and second zones and a detector.

83. (Withdrawn) The optical disc of claim 82, wherein the track is used to quantitate the amount of material in the at least one of the first and second zones.

84. (Withdrawn) The optical disc of claim 82, wherein the second zone is at least ten times larger than the first zone.

85. (Withdrawn) The optical disc of claim 82, wherein the boundaries of the chamber include smooth curves.

86. (Withdrawn) The optical disc of claim 82, wherein the disc is configured to be used to process blood.

87. (Withdrawn) The optical disc of claim 82, wherein the disc is configured to be used in determining the hematocrit of blood.

88. (Withdrawn) The optical disc of claim 82, wherein the disc is configured to be used in an analysis of white blood cells.

89. (Withdrawn) The optical disc of claim 82, wherein the disc includes freeze-dried bioactive agent material.

90. (Withdrawn) The optical disc of claim 82, wherein the main chamber includes freeze-dried bioactive agent material.

91. (New) An optical disc comprising:

an entry chamber positioned proximate a center of the optical disc and configured to contain a mixture comprising disperse particles and particle agglutinants;

a collection zone positioned proximate an outer edge of the optical disc; and

a first separation structure positioned between the entry chamber and the collection zone, the separation structure comprising a plurality of structures defining at least a first gap therebetween, a width of the at least a first gap being greater than a width of at least a portion of the particle agglutinants, and

a second separation structure positioned between the first separation structure and the collection zone, the second separation structure comprising a plurality of structures defining at least a second gap therebetween, a width of the at least a second gap being less than or equal to a width of substantially one of the particle agglutinants,

wherein the first and second separation structures are configured to separate particle agglutinants from the disperse particles when the mixture is urged toward the separation structures by centrifugal force created when the optical disc is rotated.

92. (New) The optical disc of Claim 91, further comprising:

a circular track surrounding the center of the optical disc, the track positioned at least partly beneath the entry chamber and proximate the first separation structure, wherein particle agglutinants in the entry chamber can be quantified by determining an amount of the tracking groove that is covered by particle agglutinants.

93. (New) The optical disc of Claim 91, further comprising:

a separation zone disposed radially between the first separation structure and the second separation structure;

a second tracking groove positioned at least partly beneath the separation zone and proximate the second separation structure, wherein particle agglutinants in the separation zone can be quantified by determining an amount of the second tracking groove that is at least partly covered by particle agglutinants.

94. (New) The optical disc of Claim 91, further comprising:

a plurality of tracking grooves positioned at least partly beneath the entry chamber and proximate the first separation structure, wherein particle agglutinants in the entry chamber can be quantified by determining an amount of each of the plurality tracking grooves that is covered by particle agglutinants.